**Citation:**

Yon BA, Johnson RK, Harvey-Berino J, Gold BC, Howard AB. Personal digital assistants are comparable to traditional diaries for dietary self-monitoring during a weight-loss program. *J Behav Med*. 2007 Apr; 30 (2): 165-175. Epub 2007 Jan 10.

**PubMed ID:** 17216341

**Study Design:**

Non-Randomized Controlled Trial

**Class:**

C - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To investigate whether the use of a portable digital assistant (PDA) for dietary self-monitoring would improve self-monitoring frequency and subsequent weight loss at the end of a 24-week behavioral weight loss program.

**Inclusion Criteria:**

- Over age 18 years
- Body mass index (BMI)>25 and ≤39kg/$m^2$
- Regular access to a computer, not less than three years old with:
  - CD-ROM drive
  - Internet connection
  - At least 64 Megabytes of RAM
  - 350 MHz processor speed
  - Windows 98 or higher as a computer operating system.

**Exclusion Criteria:**

- Planning a pregnancy in the next 12 months
- Planning to move from the area within the next 12 months
- History of major medical or psychiatric problems
- Taking medications that have implications for weight loss
- Unable to participate in a mild to moderate exercise program
- Unable to attend regular weekly meetings.

**Description of Study Protocol:**

**Recruitment**

- Subjects were recruited through newspaper advertisements throughout southwestern Vermont
- Interested participants were asked to enroll via a secure website developed for the study that screened out volunteers who did not meet the basic study criteria
- Existing data from a previous 24-week behavioral weight loss program, where subjects used paper diaries for dietary self-monitoring, were used for the control data.

**Design**

24-week nonrandomized controlled trial.

**Dietary Intake/Dietary Assessment Methodology**

Energy intake was measured using the Block 98.2 Food-Frequency Questionnaire (FFQ).

**Blinding Used**

The individual PDA accounts were anonymous, bearing the name assigned to the PDA by the research team.

**Intervention**

- All subjects participated in a 24-week behavioral weight loss program that focused on modification of eating and exercise habits through the use of behavioral strategies and self-management skills. Participants were instructed to reduce their energy intake by up to 1,000kcal per day, as determined by their baseline body weight. Grade goals for programmed physical activity were used throughout the program and subjects were encouraged to expend at least 1,000kcal per week
- The PDA self-monitoring group was given a Palm Zire21 PDA with the food database and self-monitoring software, Calorie King's Handheld Diet Diary software v3.2.2. PDA participants were instructed to self-monitor their food intake and exercise daily
- The control group participants were provided with small paper weekly diaries and a book with calorie listings of foods to record their food and calorie intake, as well as daily programmed exercise and calories expended.

**Statistical Analysis**

- Statistical significance was set a $P<0.05$
- Differences between groups as baseline were examined using independent samples T-tests for continuous variables and chi-square analyses and Fisher's exact tests for categorical variables
- Paired samples T-tests were used to examine differences in PDA comfort levels from baseline to six months
- Pearson product moment correlations were used to explore relationships between program components, weight-loss and dietary self-monitoring
- Repeated measures analysis of variance was used to test group differences and temporal changes in data from the food frequency and exercise questionnaires
- Ordinal data were compared within the PDA group using the non-parametric Wilcoxon Signed Rank test
- An intent-to-treat analyses, carrying forward baseline weights for non-completers, was used when comparing weight change between groups
- Analysis of covariance was used to detect differences in weight loss between groups, adjusting for significant baseline differences in BMI, as well as to examine the relationship

between self-monitoring mode, frequency and weight loss
- A number of other possible covariates were examined (marital status, education, computer comfort and fat intake) in these weight-loss analyses, but none were statistically significant
- A power analyses was conducted prior to recruiting for the PDA group. In order to detect a weight loss difference between groups at six months of 2 kg, and 11% improvement in dietary self-monitoring behavior between the PDA and control group, at alpha of 0.05 and a power of 80%, it was determined that sample size of 75 subjects per group was needed.

**Data Collection Summary:**

**Timing of Measurements**

Subjects completed a 24-week intervention period, with anthropometric and process measures being assessed at baseline and six months, while self-monitoring and compliance with study protocol was assessed weekly.

**Dependent Variables**

- Body weight, height and BMI were measured at baseline and six months
- Energy intake was measured using a Block FFQ at baseline and six months
- Computer abilities and comfort were assessed at baseline and six months.

**Independent Variables**

Attendance at group meetings, compliance with calorie and exercise goals and adherence to self-monitoring was assessed weekly by tracking the number of weeks food diaries were submitted.

**Control Variables**

- Marital status
- Education
- Computer comfort
- Fat intake
- Baseline BMI.

**Description of Actual Data Sample:**

- *Initial N*:
  - N= 61 (56 women, five men) for the PDA group
  - N=115 (96 women, 19 men) for the control group
- *Attrition (final N):*
  - N= 56 for the PDA group
  - N=93 for the control group
- *Age:*
  - PDA=48 years
  - Control=46 years
- *Ethnicity:* 100% white
- *Other relevant demographics*: At baseline, the PDA group had a significantly higher BMI, as well as more people with a high school and vocational school education, while the control group had more people who had completed some college. The control group was also more

comfortable with computers and computer technology
- *Anthropometrics:*
  - PDA mean BMI=32kg/$m^2$
  - Control mean BMI=30.9kg/$m^2$
- *Location*: United States.

**Summary of Results:**

**Body Weight Change**

- There were no significant (NS) differences in weight loss between groups for those subjects who completed all six-month measures
- An intent-to-treat analysis also found NS difference in weight loss between groups for all subjects.

| Completers | PDA | Control | |
|---|---|---|---|
| **Mean weight loss, kg** | 6.3 (6.1) | 7.2 (5.2) | (F(1,145) = 0.17, P=0.68 |
| **Mean percentage weight loss** | 7.0% (6.5) | 8.3% (5.8) | (F(1,146) = 0.99, P=0.32 |
| **All subjects** | | | |
| **Mean weight loss, kg** | 5.8 (6.1) | 5.8 (5.5) | (F(1,172) = 0.04, P=0.84 |

**Adherence to Treatment Goals**

- There were NS differences in frequency of dietary self-monitoring, attendance or compliance with calorie goals between groups
- Dietary self-monitoring was strongly associated with weight loss outcomes for completers in both groups. Thirty-two percent of the weight loss was explained by the frequency of dietary self-monitoring (F(1,144)=72.45, P<0.001), however, the relationship was not different between the two groups
- There was a significant overall relationship between attendance and weight loss (P<0.001), between compliance with calorie goals and weight loss (P<0.001), and between exercise goals and weight loss (P<0.001)
- There was a significant overall decrease in caloric intake, fat intake and percent calories consumed from fat between baseline and six months (P<0.001), but this decrease was NS different between groups
- There was a significant overall increase in exercise (P<0.001), but the increase in exercise was NS different between groups.

**Computer and PDA Abilities**

- The PDA group categorized themselves as having higher computer abilities at six months in comparison with baseline (P=0.03), so that there were no longer any significant differences in the two groups abilities at the end of the treatment program. They also reported higher comfort levels with the PDA and its applications at six months (P<0.001)
- There was a significant relationship between the participant's comfort level with the PDA at six months and the frequency of self-monitoring (P=0.01).

**Author Conclusion:**

- This study confirmed the strong relationship between dietary self-monitoring and weight loss; however, the use of a PDA did not improve that relationship
- Subjects who self-reported regularly using dietary self-monitoring tools lost significantly more weight.

***Reviewer Comments:***

*None.*

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***Research Design and Implementation Criteria Checklist: Primary Research***

| **Relevance Questions** | | |
|---|---|---|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

| **Validity Questions** | | |
|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |

| | | |
|---|---|---|
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | Yes |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |

| | | |
|---|---|---|
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |
| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | Yes |
| 6.6. | Were extra or unplanned treatments described? | Yes |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | Yes |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | Yes |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |

| | | |
|---|---|---|
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | Yes |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | Yes |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | Yes |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | Yes |
| 9.1. | Is there a discussion of findings? | Yes |
| 9.2. | Are biases and study limitations identified and discussed? | Yes |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |